## RESPONSE TO OFFICE ACTION

### A. Status of the Claims

Claims 1, 7, 8, 10-14, 17-22, 26, 27, 31-33, 35-41, 43-45, 49-52, and 54 were pending. Claims 7, 26, and 36 are canceled without prejudice. Claim 37 is amended herein. Support for the amendment is found in the Specification, for instance at Example 5 and Example 9. Claims 1, 8, 10-14, 17-22, 27, 31-33, 35, 37-41, 43-45, 49-52, and 54 are presented herein for reconsideration.

### B. Objection to the Claims

Claims 7 and 20 were objected to under 37 C.F. R. 1.75(c) as being improper for failing to further limit the subject matter of a previous claim. Claim 7 is canceled herein; in view of this the rejection of claim 7 is moot, and its withdrawal is respectfully requested. Regarding the rejection of claim 20, it is believed that this represents a typographic error, and that claim 26 was properly subject to the objection, in view of the Action at page 3, last sentence of first full paragraph. Claim 26 is canceled herein. In view of this, the rejection of claim 26 is believed to be moot and its withdrawal is respectfully requested.

### C. Rejections Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1, 7, 14 and 17-19 as failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. The Action acknowledges that the application provides written description of the "formation of embryogenic cotton callus" and "any regenerable cotton tissue," but asserts that written description is lacking for "regenerable embryogenic callus tissue" as recited in claims 1 and 14, in that the claimed subject matter is not described in such a way as to convey to a skilled worker that the inventors had possession of the claimed invention at the time of filing of the application. Applicants respectfully traverse.

Applicants submit that the cancellation of claim 7 renders the rejection moot with respect to that claim. Also, Applicants note again that, although the specification does not use the precise sequence of terms "regenerable embryogenic callus tissue," this subject matter is fully described in the specification. *See*, for example, page 32 lines 6 through page 33, line 7. **There is no requirement to describe a literal sequence of claimed terms**. Both M.P.E.P. and the relevant case-law has repeatedly have made it clear that an applicant's specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement, as long as the skilled reader understands that the text, taken as a whole, conveys the same meaning. *See Ex Parte Sorenson*, 3 U.S.P.Q.2d 1462, 1463 (Bd. Pat. App. & Interf. 1987). *See* M.P.E.P. 2163 (I) (B). An analysis of whether a specification provides an adequate written description of a claimed invention requires one to read the complete specification to determine whether "the text as a whole" conveys the invention. *See Union Oil Co. v. Atlantic Richfield Co*., 208 F.3d 989, 996 (Fed. Cir. 2000).

Here, the summary and Examples, as a whole, describe induction of embryogenic cotton callus, maturation of embryogenic cotton callus, embryo germination, and a media used to germinate mature embryos into plants. *See* Summary and Examples in the Specification. This is, at the very least implicitly and inherently, a description of regenerable embryogenic cotton callus tissue. For example, page 32 lines 6 through page 33, line 7 of the specification describe the following:

> Embryos were induced as outlined in Examples 2, 3, and 4. After eight weeks, the embryogenic tissue that formed was transferred to an embryo maturation media as described in Examples 5 and 6. Cultures were monitored for the presence of actively growing embryos.
>
> About every four weeks, actively growing tissue and small embryos were removed and placed on fresh maturation media. The embryos were spaced on the culture plates with adequate room for growth. The tissue was returned to the warm room and incubated under the same growth conditions.
>
> Embryos larger than about 5 mm were transferred to a germination media (Stewart and Hsu, Planta 137:113-117, 1997) with various carbohydrate

concentrations and 0.25 g/L GELRITE. The embryos are incubated at 28°C. in a lighted incubator with a 16/8 day/night cycle.

Various concentrations of glucose and sucrose in the germination media were tested. The germination media comprised sucrose or glucose at concentrations ranging from about 0%-2% (w/v). The results demonstrated that using germination media containing glucose or sucrose concentrations ranging from about 0% to 0.5% (w/v) significantly increased the frequency of embryo germination and plantlet formation (Table 10).

After embryos had germinated and developed about 3-4 leaves, the tissues were transferred to a larger container containing the same germination media. Once the plants developed 4-6 total leaves, they were transferred to pots containing Metro-Mix 350 and slowly hardened off.

Further, originally filed claim 58, now cancelled, recited the steps of a method for preparing transgenic cotton plants, as follows:

> 58. A method for the preparation of transgenic cotton plants comprising: (a) culturing transformed regenerable non-embryogenic cotton callus tissue in media containing an antioxidant and an ethylene inhibitor under dark lighting conditions, limited lighting conditions, or under green light, to produce transgenic embryogenic cotton tissue; (b) culturing the transgenic embryogenic cotton tissue in media containing a support matrix and amino acid hydrolysate supplement under dark lighting conditions, limited lighting conditions, or under green light and wrapped in a sealing material, to produce transgenic cotton embryos; and (c) culturing the transgenic cotton embryos in germination media containing glucose or sucrose, wherein the concentration of the glucose or sucrose is at a concentration between about 0.05% (w/v) and about 1% (w/v).

In particular, in step (a) regenerable non-embryogenic cotton callus tissue is treated to induce production of embryogenic tissue; in step (b) the embryogenic tissue is further treated to induce production of embryos; and in step (c) the embryos are germinated (producing plantlets). Thus for instance, as a whole, steps (a)- (c) of original claim 58, as well as the Specification for instance at pages 32-33 as previously noted, describe "regenerable embryogenic callus tissue." That is, the tissue of step (b) is explicitly described as being "embryogenic", while steps (b)- (c) indicate that such tissue may be treated to result in germinated embryos (*i.e.* differentiated plantlets)- **and is thus regenerable tissue**.

Additionally, the Specification, for instance in the Background of Invention section (*e.g.* at page 2, lines 23-29) further makes it clear that nonembryogenic cotton tissue may be induced to form embryogenic cotton calli, and the embryogenic cotton calli may then be treated to form, mature, and germinate embryos, and to form plants. This process is further described in the Examples, for instance in Example 9, wherein plantlets are generated from transformed cotton cells. The process wherein callus cells grow and differentiate to eventually form a plant **is the process of regeneration**, and callus cells that are able to undergo this process that ultimately results in the production of plants **are known to be "regenerable"** in the art. Thus, one skilled in the art would recognize that the applicant had possession of the claimed invention.

Finally, M.P.E.P. 2163 (I) (B) states: "While **there is no *in haec verba* requirement**, newly added claim limitations must be supported in the specification through **express, implicit, or inherent** disclosure (emphasis added), and later, "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117." In this instance, these requirements are clearly met. Namely, as discussed above, the Specification provides, at the very least, implicit and inherent disclosure of regenerable embryogenic cotton callus tissue, and one of skill in the art would understand this to be the case.

The specification thus fully describes embryogenic callus tissue and regenerating plantlets from the embryogenic callus tissue. The Action asserts at page 4 that the passage at pages 32-33 of the Specification "does not describe the regenerable embryogenic cotton callus tissue." However, since the described embryogenic callus tissue **had the ability to regenerate** into plantlets, one of skill in the art would clearly recognize that tissues described or used at pages 32-33 (Example 8), as

well as, for instance, at pages 33-34 (Example 9; *e.g.* Table 11) and in original claim 58, are, in fact, regenerable embryogenic callus tissue. Therefore, the specification complies with the written description requirement. Applicants respectfully request that this rejection of claims 1, 14, and 17-19 be withdrawn.

**D. Rejections Under 35 U.S.C. § 103(a)**

**(1) Rejection of claims 1 and 7 in view of Finer and Rangan**

The Action rejects claims 1 and 7 over Finer (Canada Patent 1,309,367) in view of Rangan (U.S. Patent 5,834,292). Applicants respectfully submit that the rejection of claim 7 is moot in view of the cancellation of that claim. Regarding claim 1, Applicants respectfully traverse.

The Action asserts that Finer teaches a method of producing pro-embryonic cotton cell masses that are capable of regenerating into mature embryos. The Action further asserts that callus formed from an explant such as a hypocotyl may be organized or non-organized, and may contain embryogenic callus and/or embryos (Finer, page 7, 5th paragraph). However, Applicants respectfully submit that this is a mischaracterization of the cited reference. In particular, Finer at page 7, 5th paragraph, explicitly states that when hypocotyls or cotyledons are used as explant sources, the callus that forms is **unorganized** *i.e.* lacking in pro-embryonic cell masses, and thus is non-embryogenic. In contrast, when somatic embryos are used as explant sources, then the callus which forms may include embryogenic callus. **Finer does not teach conversion of cotton callus tissue, derived hypocotyl tissue, from a non-embryogenic state to an embryogenic state.** Rather, at page 7, 5th paragraph Finer is stating that embryogenic tissue can give rise to embryogenic callus, while non-embryogenic tissue (*e.g.* hypocotyl) remains non-embryogenic. Thus, instead of teaching that callus induced from hypocotyl tissue is embryogenic, a skilled artisan would understand that Finer clearly teaches the opposite. Since the Action at page 5 states that the

claims are drawn to "a method of inducing the formation of regenerable embryogenic callus tissue from non-embryogenic cotton callus tissue...," *i.e.* producing embryogenic tissue from non-embryogenic tissue, Finer in no way renders the claims obvious. Applicants respectfully submit that a *prima facie* case for obviousness has not been made, and withdrawal of rejections made in view of Finer is respectfully requested.

With regard to the assertions in the third paragraph on page 5 of the pending Action, that Finer teaches induction of callus, and production, maturation and germination of embryos, including in the dark, Applicants submit that distinct tissue sources and culture steps of Finer are being conflated or confused in this summary. For instance, the Action appears to imply that a hypocotyl explant may be utilized, callus may be induced from such as explant, and that ultimately embryogenic callus, embryos, and plantlets are produced from this explant source as well. However, Finer does not state this at the cited passages (*e.g.* page 7, 5$^{th}$ paragraph; page 8, 2$^{nd}$ paragraph; page 9, 2$^{nd}$ paragraph; page 10, 4$^{th}$ paragraph; page 11; page 12, 3$^{rd}$ - 4$^{th}$ paragraphs). Again, while callus may be induced from hypocotyl tissue, Finer states that this callus would be unorganized and does not contain pro-embryonic cell masses. Thus it is not embryogenic. Instead, Finer describes use of somatic embryos, apparently taken before primary leaf expansion (page 5, 4$^{th}$ paragraph), or certain other tissue but not hypocotyl tissue, as explants for production of pro-embryonic cell masses and, eventually, embryos and plants. Embryogenic callus and/or embryos derived from hypocotyl tissue therefore represent **unexpected results** in view of Finer.

The Action also cites Rangan (U.S. Patent 5,834,292) as teaching transformation of callus tissue. While Applicants acknowledge that Example 20 of Rangan discusses transformation of cotton callus, Applicants do not concede that it discusses transformation of embryogenic callus, or that such transformation or culture and growth subsequent to the transformation, occurred in the

dark. Instead, Rangan explicitly teaches, *e.g.* at column 7, lines 8-10; column 8, around line 30, as well as at column 26, line 37, that culture of callus cells is to occur under a 16:8 hour light:dark regime. Thus, contradicting the assertion of the Action at page 6, 2nd paragraph, the Rangan reference is **teaching away** from utilizing dark conditions as is presently claimed. Further, the Action asserts at page 6 that Rangan Example 26 describes transformation of cotton cells to produce plants. Applicants can find no such disclosure in Example 26. Instead, the Table in Example 26 is not describing production of transformed plants from transformed cells. Instead, it is describing, for instance in column labeled "C" and "P", **transformation** of callus tissue or (differentiated) plant tissue, respectively, followed by induction of callus from selected transformed tissue, for instance as discussed in Example 18.

Further, in this and subsequent rejections, the Action repeatedly states that "...one of ordinary skill in the art...would have had a reasonable expectation of success in the combination... because [the conditions] would be a choice of experimental design and is considered within the purview of the cited prior art." Applicants submit this assertion represents circular, unclear, conclusory, and tainted-by-hindsight reasoning. Applicants respectfully request that a reasonable basis for any alleged "expectation of success" be provided for each of the asserted objections.

Further, given the many possible experimental details pertaining to tissue sources, developmental stage, embryogenic ability, regenerability, as well as hundreds, if not more, possible variations in tissue culture conditions (*e.g.* temperature; lighting length, quality, and intensity; media components, timing of steps, *etc.*, that are discussed in these cited references let alone the art of cotton cell culture as a whole), the number of possible variations is essentially unlimited, and one of skill in the relevant arts would have had **no expectation of success** in choosing, for instance, the variable regarding culture under dark conditions from among the numerous experimental variables.

Indeed, it is not even clear that Finer teaches induction of regenerable embryogenic cotton callus from hypocotyls (non-embryogenic tissue) in the dark, since as noted above, Finer at page 8, 1st paragraph, is not discussing production of embryogenic callus from hypocotyls, and also states that use of light (apparently continuous light) is preferred when working with pro-embryonic cell masses (that, as previously discussed, are not derived from hypocotyls), while Rangan teaches that an alternating light:dark regime is to be used. Thus, the conclusion of the Action, that Finer and Rangan render obvious the presently claimed invention, is based on hindsight reasoning, and is mistaken in view of the unexpected results, lack of expectation of success, and teaching away in the art. Withdrawal of the rejection is respectfully requested.

**(2) Rejection of claims 8, 10-12, under 35 U.S.C. § 103(a).**

The Action rejects claims 8, and 10-12 under 35 U.S.C. § 103(a) as being unpatentable over Firoozabady *et al.,* (*In Vitro Cell Dev. Biol.*, 299:166-178 (1993) ("Firoozabady 1993")), in view of Davis *et al.,* (*In Vitro* 9:395-398, 1974 ("Davis")). Claim 8 is directed to inducing embryogenic calli from regenerable non-embryogenic calli in presence of an antioxidant in culture media. Claims 10-12 are dependent claims that depend from claim 8. The Action asserts that Firoozabady 1993 teaches culturing **non-embryogenic** (emphasis added) cotton callus under dark conditions, and Davis teaches adding ascorbic acid in a medium to form cotton callus tissue. The Action finds it would be *prima facie* obvious to one of skill in the art to combine the cited references to arrive at the presently claimed invention. Applicants respectfully traverse.

Applicants note that Firoozabady 1993 states, at page 169, right column, last paragraph, that different phases of cotton tissue culture (*e.g.* non-embryogenic, embryogenic) are affected (differentially) by various light and temperature conditions. Given the numerous experimental details that might potentially affect callus induction, growth, organization, and development, for

instance in choosing from among parameters such as explant source (*e.g.* cultivar, tissue type, age); method of isolation of tissue; culture conditions (numerous media recipes and variants relating to C source, N source, major and minor salts, growth hormone levels and ratios, other components, *etc.*); temperature; lighting quality, intensity, and duration; length of time of culture; changing of media; *etc. etc.,* the assertion of the action that it would have been obvious to combine the teachings of Firoozabady (1993) with Davis represents hindsight reasoning.

Although the Action at pages 8-9 states that Davis teaches that adding ascorbic acid enhanced the growth of cotton callus tissue by reducing the formation of pigments in the callus tissue, Applicants respectfully submit that cited art indicates that this would apply, if at all, to non-embryogenic cultures, and is contradicted by other art with respect to embryogenic cultures. As noted previously, Davis is only concerned with non-embryogenic callus, while Firoozabady (1993) is stated to teach a method of inducing regenerable non-embryogenic cotton callus tissue (Action, page 8) as well. However, Rangan (U.S. 5,834,292), at column 8, lines 58-64, states that pigmentation is a useful marker for following callus growth, and development of the embryogenic state. Thus, Rangan **teaches away** from the Action's assertion that reduction of pigmentation would be of benefit, at least for development of embryogenic cultures (with which, as previously noted, Davis is not concerned). Since the present claims relate to inducing formation of embryogenic callus, the references, in view of Rangan, do not render obvious claims 8 and 10-12. Withdrawal of the rejection is respectfully requested.

**(3) Rejection of claim 13 under 35 U.S.C. § 103(a).**

The Action rejects claim 13 over Firoozabady (1993) in view of Davis as applied to claims 8 and 10-12, and further in view of Rangan, apparently in that Rangan teaches transformation of cotton callus tussue. Applicants respectfully traverse.

As noted above with respect to claims 8 and 10-12, Rangan **teaches away** from reducing pigmentation of callus cultures when embryogenic callus is to be produced, because reduced pigmentation could interfere with the ability to correctly distinguish embryogenic and non-embryogenic callus tissues (Rangan, column 8, lines 58-64). Therefore, withdrawal of the rejection is respectfully requested.

**(4) Rejection of claims 14, 17, and 18 under 35 U.S.C. § 103(a).**

The Action rejects claims 14, 17, and 18 as being unpatentable over Firoozabady 1993 in view of Chi (*Pl. Cell Rep.* 9:195-198, 1990). The Action asserts that Chi teaches adding AVG for regeneration. The Action finds it would be *prima facie* obvious to one of skill in the art to combine the cited references to arrive at the invention. Applicants respectfully traverse.

Applicants initially note again that (1) *Brassic*a species are not closely related to cotton plant species; (2) *Brassica* typically regenerate via **organogenesis rather than embryogenesis**; and (3) the AVG treatment discussed in Chi showed variable results when applied within the Brassicaceae. Thus as noted in the prior two responses, a skilled worker would have had **no expectation of success** in applying Chi, in view of Firoozabady, to a method for producing embryogenic cotton callus. The present Action does not refute or even address this argument when it conclusorily states that the Chi reference can not be attacked individually.

Applicants respectfully submit that the Action provides no rationale as to how application of Chi would be applied to Firoozabady 1993 in view of these previous arguments by the Applicants. Further, at page 12 the Action states that "it would have been a design choice to use AVG...knowing that AVG has an effect of tissue culture whether the plants are monocots or dicots." However, the "effect" of AVG is not defined in the Action, except that the Action characterizes Chi *et al.* to "teach that AVG enhanced shoot regeneration…" (Action, page 10, last paragraph). Applicants

note that shoot regeneration is an example of **organogenesis**, and not embryogenesis as is required in the present claims. Thus the Action itself demonstrates the inapplicability of Chi to the present claims, essentially as argued in the previous response. Additionally, even if Chi is correctly characterized as enhancing shoot regeneration, then this would render a method of Firoozabady (1993) in view of Chi to be **inoperable**, in that organogenic regeneration would interfere with an attempt to regenerate cotton by an **embryogenic** approach, since organized tissues such as shoots would be produced, instead of embryogenic callus and eventually embryos. Results of a method of Firoozabady in view of Chi would also be **unpredictable**, as it would be unclear what effect any development of organized shoot tissues (in view of the teachings of Chi with respect to AVG application) would have on somatic embryogenesis. Alternatively, Applicants submit that an organogenic method in view of the Chi reference, even if operable (which Applicants do not concede, except *in arguendo*) would render the Firoozabady reference **unsatisfactory for its intended purpose** (*i.e.* an embryogenic approach for cotton tissue culture) and would **change the principle of operation** of the teachings of Firoozabady, by substituting organogenesis for an embryogenic callus based approach (MPEP 2143.01; 2145 (X) (D)). This is not in accord with Office procedure, and thus a *prima facie* case of obviousness has not been made. Withdrawal of the rejection is respectfully requested.

Further, Applicants note that the arguments in the previous responses do not discuss an effect of AVG in dicots versus monocots, and that both Brassicaceae and *Gossypium* spp. are dicots. Thus the Action's assertions regarding monocot plants are unclear, not apt, and also do not address the Applicant's arguments of the last two responses. Applicants also do not concede that Chi shows AVG to be of use in embryogenic cotton tissue culture, or that the Action shows this to be the case.

For this reason as well, a *prima* facie case of obviousness still has not been established, and Applicants respectfully request that the rejection of the claims be withdrawn.

**(5) Rejection of Claim 19 under 35 U.S.C. § 103(a).**

The Action rejects claim 19 under 35 U.S.C. § 103(a) over Firoozabady (1993) further in view of Chi, as applied to claims 14, 17, and 18, and further in view of Rangan. Applicants traverse, and note that the addition of Rangan with respect to claim 19, apparently in view of its asserted teachings regarding transformation, does not cause the Chi reference to be any less irrelevant to embryogenic cotton cell culture. In view of the arguments in (4) above, withdrawal of the rejection is respectfully requested.

**(6) Rejection of Claims 20-22, 26, and 27 under 35 U.S.C. § 103(a)**

The Action rejects claims 20-22, 26, and 27 over Finer in view of Rangan, further in view of Davis and further in view of Chi. Regarding claim 26, applicants submit that the rejection is moot in view of the cancellation of that claim. With regard to claims 20-22, and 27, Applicants traverse as follows:

Applicants note that the Action characterizes claims 20-22, 26, and 27 as reciting that callus tissue is derived from hypocotyl tissue. However this is not the case, and Applicants respectfully request clarification.

As noted above, Finer in view of Rangan **teaches away** from use of dark conditions to culture cotton callus. On the contrary, Rangan teaches that a 16:8 light:dark period should be used. As also noted above, Rangan utilizes pigmentation (or lack thereof) as a marker to recognize development of embryogenic callus. Thus Rangan teaches away from the Action's asserted reason for use of the teachings of Davis, to reduce formation of black pigment in cultured cells. Additionally, as noted above, Chi is not apt or operable with respect to use of an ethylene inhibitor

for induction of embryogenic callus tissue since it discusses an organogenic approach, such as shoot regeneration as characterized in the Action, and as cited at Chi, page 197, right column, 3rd paragraph. Applicants again note that shoot regeneration is an example of organogenesis, and not embryogenesis. Thus Chi, if applied, must *prima facie* teaches away from an embryogenic approach to plant regeneration (for instance see comparison table at page 16 of the prior response). Since a skilled artisan would not understand how the teachings of Chi are relevant to an approach as described by Finer, Rangan, or Davis, there would be **no expectation of success** in applying the teachings of Chi. The Action's assertion to the contrary is conclusory, and no sound technical or logical basis for such a conclusion has yet been provided to the Applicants. In total, no *prima facie* basis for the obviousness rejection has been established, and withdrawal of the rejection is respectfully requested.

**(7) Rejection of Claims 31-33 and 35 under 35 U.S.C. § 103(a)**

The Action alleges that claims 31-33 and 35 are unpatentable under 35 U.S.C. § 103(a) over Finer in view of Rangan, also in view of Davis and further in view of Chi as applied to claims 20-22, 26, and 27, and further in view of Firoozabady *et al.*, 1987, *Plant Molecular Biology*, vol. 10, pages 105-116 ("Firoozabady 1987"). The Action asserts that Firoozabady 1987 teaches culturing cotton tissue on a support matrix such as filter paper. The Action finds it would be *prima facie* obvious to one of skill in the art to combine the cited references to arrive at the invention. Applicants respectfully traverse.

Applicants traverse the combination of Finer, Rangan, Davis, and Chi as repeatedly discussed above. This combination of references, as well as the addition of Firoozabady 1987, represents hindsight reasoning. As well, Rangan **teaches away** from culture in dark, and from use of an antioxidant to avoid production of dark pigment, as asserted by the Action. Thus, combining

Finer, Rangan, and Davis would yield no **expectation of success** for a skilled worker. Likewise, Chi is not apt or operable, as also discussed above, and would likewise yield no **expectation of success** for a skilled worker.

As discussed in previous responses, Firoozabady 1987 only describes use of filter paper for transformation during co-culture of cotyledon pieces with *Agrobacterium.* This is an early step in the overall transformation and regeneration process, and the use of filter paper is specifically described as being in order to avoid overgrowth of bacteria on plant tissues (*e.g.* Firoozabady, page 107, right column; 2nd full paragraph). Embryogenic cotton tissue is not being placed on filter paper; rather, cotyledon pieces are being placed on filter paper. This is conceded by the Action at page 14, last sentence. After the co-cultivation step, Firoozabady 1987 teaches that plant tissues then be transferred to growth medium **without** filter paper (page 107, right column, 3rd full paragraph). This **teaches away** from use of filter paper during steps subsequent to co-cultivation. Use of a support medium during co-culture is distinct from use of a support medium during embryo maturation. The Action provides no teachings in any cited reference that embryogenic cotton tissue may be cultured **on an embryo maturation medium with a support matrix**, as is claimed.

Applicants again note that the step in Firoozabady 1987 that would be most comparable to the presently claimed use of filter paper is actually found at page 108, first paragraph left column, section entitled "Regeneration of transgenic plants." In this section, Firoozabady 1987 describe induction of embryogenesis in previously transformed (but non-embryogenic) callus, to produce and germinate somatic embryos. No use of filter paper **at this stage** is taught or contemplated by Firoozabady 1987. Thus it is unclear to Applicants how the teachings of Firoozabady 1987 would lead to any **expectation of success** in practicing the presently claimed invention, even if they were applied, and no *prima facie* case of obviousness has been established. Applicants respectfully

submit that the present rejection and reasoning behind the rejection, to the extent they are understood by Applicants, appear to relate to methods that are not being claimed. Thus the relevance of this rejection is entirely unclear. In view of the above, withdrawal of the rejection is respectfully requested.

**(8) Rejection of Claims 36-38 under 35 U.S.C. § 103(a)**

The Action rejects claims 36-38 as being unpatentable over Strickland (U.S. Patent 5,846,797) in view of U.S. Patent No. 5,244,802, issued to Rangan ("Rangan"). The Action asserts that Rangan teaches adding hydrolysate to promote formation of somatic embryos. Applicants respectfully traverse in part, while noting that claim 36 is canceled and claim 37 is amended. The rejection of claim 36 is believed to be moot, and its withdrawal is respectfully requested.

As an initial matter, Applicants note that the citations to Rangan that are given in the Action at page 16, 2nd paragraph, do not appear to match the specification of Rangan. Clarification is respectfully requested.

Applicants also respectfully submit that Strickland relates to cotton callus production on media lacking exogenous plant hormones (Strickland abstract; Action page 15 last sentence). Thus its relevance is unclear, and there would be **no expectation of success** in applying its teachings, especially since claim 36 is canceled, and claim 39 recites use of an ethylene inhibitor, which would alter plant hormone levels effectively in contradiction to the teachings of Strickland. Further, the addition of casein hydrolysate that is described by Rangan occurs when tissues are placed on Beasley and Ting **embryo germination** medium. That is, Rangan is teaching the use of casein hydrolysate well after formation of embryogenic callus and embryos, instead at the later step of inducing mature embryos to germinate. Such embryos of Rangan are also not being grown in dark conditions, or in the presence of an antioxidant, an ethylene inhibitor, or a support matrix, and the

cited combination of references is based on hindsight reasoning in that it focuses on a handful of parameters to the exclusion of an essentially unlimited number of other possible combinations of all possible tissue culture parameters. In view this, as well as the claim amendments, the rejection is believed to be moot and/or mistaken, and its withdrawal is respectfully requested.

**(9) Rejection of Claims 39-41, 43 and 44 under 35 U.S.C. § 103(a)**

Claims 39-41, 43, and 44 are rejected under 35 U.S.C. § 103(a) as unpatentable over Finer in view of Davis, further in view of Chi, further in view of Firoozabady 1987, and further in view of Rangan. The Action finds it would be *prima facie* obvious to one of skill in the art to combine the cited references to arrive at the invention. Applicants respectfully traverse.

Applicants submit that the Finer, Davis, Chi, Firoozabady 1987, and Rangan references do not render these claims obvious, for the reasons discussed above. Among the numerous parameters relating to cotton cell tissue culture to produce callus, both non-embryogenic and embryogenic, these multiple reference provide diverse and often inapplicable or contradictory teachings, that teach away from each other. For instance, unlike Finer, culture in an alternating period of light:dark is taught by Rangan. Likewise, Finer teaches a method in which cotyledon tissue does not yield embryogenic callus. Firoozabady 1987 teaches use of filter paper with cotyledon pieces (non-embryogenic, non-callus tissue) during co-culture with *Agrobacterium*, but not subsequent to this step. Chi teaches use AVG in an organogenic approach, while the present specification as well as the other references discuss embryogenic approaches for tissue culture, which Applicants submit would impermissibly change a fundamental principle in the operation of the claimed method (M.P.E.P. 2143.01 (VI)). Thus, combining such references would provide **no expectation of success** to a skilled artisan, especially because it would be entirely unclear, without hindsight, which teachings from which references should be utilized.

Applicants further note that the Action at page 18 asserts that use of filter paper "would ease in transporting the tissue." Applicants can find no teachings to this effect in cited references, and respectfully request clarification.

In view of the many possible variables in such plant cell culture experiments and also the limitations of claims 39-41, 43, and 44, one of skill in the art of plant cell culture would also have had no motivation to combine the teachings of Firoozabady 1993 and Rangan. Even if the references were combined, in total, and as noted above, they teach away from use of limitations recited in these claims. In view of the above, the cited references therefore neither teach nor suggest all elements of the claims to one of skill in the art, and a *prima facie* case of obviousness has not been established. Applicants respectfully request that the rejection of claims 39-41,43, and 44 be withdrawn.

**(10) Rejection of Claims 45 and 49 under 35 U.S.C. § 103(a)**

The Action rejects claims 45 and 49 under 35 U.S.C. § 103(a) as being unpatentable over Finer in view of Rangan as applied to claims 1 and 7, and further in view of Gould (*Pl. Cell Rep.* 10:12-16, 1991). The rejection apparently relates to use of a sealing material. The Action finds it would be *prima facie* obvious to one of skill in the art to combine the cited references to arrive at the invention. Applicants respectfully traverse.

Applicants note that the Action asserts that wrapping a culture with laboratory film would be desirable to prevent evaporation and contamination (Action, page 19, 3rd line). Applicants find no specific basis for this conclusion. Indeed, such a conclusion apparently contradicts teachings in the art. However, since this has been asserted, Applicants respond that the art has noted that a step of desiccation may be helpful for recovery of cotton plantlets from somatic embryos (*e.g.* see Appendix 2 of inventor's affidavit filed in this case on April 5, 2007: abstract by Sakhonokho *et al.*,

for *Pl. Cell Rep.* 40:177-181, 2004). Thus Applicants submit that this asserted basis for wrapping a culture with laboratory film is apparently mistaken, or at least an oversimplification of the art, and a skilled worker would not inevitably have come to the same conclusion. On the contrary, avoiding evaporation may yield **unexpected results** in view of Sakhonokho *et al.* Applicants also note that Gould relates to an organogenic approach for cotton plant or cell culture, and that multiple conditions utilized by Gould would differ from those that might be utilized during cotton cell embryogenesis as presently described. Thus any asserted teachings of **Gould would not give a skilled worker an expectation of success** if they were to be applied to cotton embryogenesis. Therefore the rejection is without basis, and its withdrawal is respectfully requested.

As noted above and in previous responses, Gould relates to culture of shoot apical meristems, and would not be applied by one of skill in the art regarding embryogenic cotton cell culture, given the numerous differences between the work of Gould and the other cited references, as well as the numerous defects regarding combining the other cited references. Applicants submit that it would not be clear to a skilled practitioner which of the numerous contradictory teachings among these references to pick and choose to arrive at the presently claimed invention. The cited references therefore neither teach nor suggest all elements of the claims to one of skill in the art. The references in total also do **not give a skilled practitioner any expectation of success**, and teach away from the claimed method in numerous instances outlined above. Applicants respectfully request that the rejection be withdrawn.

**(11) Rejection of Claims 50-52 and 54 under 35 U.S.C. § 103(a)**

The Action rejects claims 50-52 and 54 under 35 U.S.C. § 103(a) as being unpatentable over Finer in view of Davis, further in view of Chi, further in view of Rangan, further in view of

Firoozabady 1987 as applied to claims 39-41, 43, and 44, and further in view of Gould. Applicants respectfully traverse.

The Action apparently relates to use of a sealing material. As noted above, and in previous responses for many of these references, Applicants submit that, absent impermissible hindsight, it would not be clear to a skilled practitioner which of the numerous contradictory teachings from among these references would be of use to arrive at the presently claimed invention. The addition of Gould, far from clarifying or simplifying, introduces another profoundly distinct experimental approach (organogenic culture) and additional parameters that might be tested.

Regarding use of a sealing material, the Action asserts that a desire to reduce contamination would motivate a practitioner to combine the Gould reference with the other cited references. Applicants note that it is unclear why preventing evaporation (as asserted in (10) above) would not also be a motivation, *in arguendo*, in view of the Action at page 19, top paragraph. Applicants submit that the discussion of (10) is also relevant here, and thus a skilled practitioner **would not have any expectation of success** in wrapping a culture with sealing material. Further, wrapping a culture (or a plate containing a culture), in addition to affecting the hydration of a culture, could also affect gas exchange, *e.g.* levels of $CO_2$, and thus other aspects of cell metabolism and growth. Therefore a skilled practitioner would not have expected that wrapping with a sealing material would be beneficial, *i.e.* there would have been **no expectation of success** in practicing the claimed methods. Applicants respectfully request that the rejection be withdrawn.

**E. Conclusion**

In view of the above, it is submitted that all of the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned at (214) 259-0931 with any questions, comments, or suggestions relating to the references patent application.

Respectfully submitted,

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